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The Brussels consensus for non-invasive ICP monitoring when invasive systems are not available in the care of TBI patients (the B-ICONIC consensus, recommendations, and management algorithm)

Chiara Robba[1,2,47*], Edoardo Picetti[3], Sebastián Vásquez-García[4,5,46], Yasser B. Abulhasan[6], Amelia Ain[7], Amos O. Adeleye[8,9], Marcel Aries[10,48], Sérgio Brasil[11], Rafael Badenes[12,13], Alessandro Bertuccio[14], Pierre Bouzat[15], Luis Bustamante[16], Lorenzo Calabro'[17], Hassane Njimi[17], Danilo Cardim[18], Giuseppe Citerio[19], Marek Czosnyka[20], Thomas Geeraerts[21], Daniel A. Godoy[22], Mohammad I. Hirzallah[23], Bhagavatula Indira Devi[24], Manuel Jibaja[25], Piergiorgio Lochner[26], Julio C. Mijangos Méndez[27], Geert Meyfroidt[28], Thangaraj Munusamy[29], Juan Pinedo Portilla[30], Hemanshu Prabhakar[31], Frank Rasulo[32,33], Diana M. Sánchez Parra[34], Aarti Sarwal[35], Gentle S. Shrestha[36,49], Dhaval P. Shukla[37], Gene Sung[38], Abenezer Tirsit[39,44], Franly Vásquez[40], Walter Videtta[41], Yu Lin Wang[42], Wellingson S. Paiva[43], Fabio Silvio Taccone[17] and Andres M. Rubiano[44,45,46]

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Abstract

Background: Invasive systems are commonly used for monitoring intracranial pressure (ICP) in traumatic brain injury (TBI) and are considered the gold standard. The availability of invasive ICP monitoring is heterogeneous, and in low- and middle-income settings, these systems are not routinely employed due to high cost or limited accessibility. The

*Correspondence: kiarobba@gmail.com
[47] Anesthesia and Intensive Care, IRCCS for Oncology and Neuroscience, Policlinico San Martino, Genoa, Italy
Full author information is available at the end of the article

Chiara Robba, Edoardo Picetti, Sebastián Vásquez-García , Fabio Silvio Taccone and Andres M. Rubiano have contributed equally to this work.

Endorsed by: **The European Society of Intensive Care Medicine (ESICM)** The Neurotraumatology Committee of the World Federation of Neurosurgical Societies (WFNS); The Neurotraumatology and Intensive Care Chapter of the Latin American Federation of Neurosurgical Societies (FLANC); The Latin American Brain Injury Consortium (LABIC); The Global Health Research Group in Acquired Brain and Spine Injuries (GHRG-BSI); The Global Neuro Foundation (GNF); The Foundation for Medical Emergency Research and Education (MEDITECH); The Society of Neurocritical Care (SNCC); The International Pan Arab Critical Care Medicine Society (IPACCMS).

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aim of this consensus was to develop recommendations to guide monitoring and ICP-driven therapies in TBI using non-invasive ICP (nICP) systems.

Methods: A panel of 41 experts, that regularly use nICP systems for guiding TBI care, was established. Three scoping and four systematic reviews with meta-analysis were performed summarizing the current global-literature evidence. A modified Delphi method was applied for the development of recommendations. An in-person meeting with group discussions and voting was conducted. Strong recommendations were defined for an agreement of at least 85%. Weak recommendations were defined for an agreement of 75–85%.

Results: A total of 34 recommendations were provided (32 Strong, 2 Weak) divided into three domains: general consideration for nICP use, management of ICP using nICP methods and thresholds of nICP tools for escalating/de-escalating treatment. We developed four clinical algorithms for escalating treatment and heatmaps for de-escalating treatment.

Conclusions: Using a mixed-method approach involving literature review and an in-person consensus by experts, a set of recommendations designed to assist clinicians managing TBI patients using nICP systems plus clinical assessment, in the presence or absence of brain imaging, were built. Further clinical studies are required to validate the potential use of these recommendations in the daily clinical practice.

Keywords: Non-invasive intracranial pressure, Traumatic brain injury, Transcranial Doppler, Automated pupillometry, Optic nerve sheath diameter

Introduction

Intracranial hypertension causes secondary brain damage after traumatic brain injury (TBI) and is associated with high rates of mortality and poor neurological outcomes [1–4].

Invasive monitoring methods—i.e., intraparenchymal and intraventricular systems—are considered the gold standard to measure intracranial pressure (ICP), for guiding TBI management and for defining intensity of treatment, escalating or de-escalating therapeutical interventions [5–8].

A recent Consensus with a management algorithm [The Seattle International Severe Traumatic Brain Injury Consensus Conference (SIBICC)] provided a comprehensive approach for severe TBI management based on ICP monitoring, which consists of 18 interventions, with different tiers, based on progressively higher intensity of treatment and high-risk therapies [9]. However, the use of invasive ICP tools is very heterogeneous across different world regions, with limited use mostly in low-income countries, where these tools are considered expensive and often unavailable [3]. In addition, sometimes patients have contraindications for invasive ICP monitoring because of high risk of bleeding and/or coagulopathy [6].

The Benchmark Evidence from South American Trial—Treatment of Intracranial Pressure (BEST-TRIP) trial, where patients were randomized to receive protocolized care based either on invasive ICP monitoring or on clinical examination and brain imaging [i.e.,The Imaging and Clinical Examination (ICE) protocol], found no differences in outcomes between groups [10, 11]. However, the primary outcome selected was a composite one and the trial was not powered for a singular neurological outcome. Additionally, the secondary outcome was mortality which is not patient-centered.

Take-home messages

34 recommendations were provided regarding general consideration for nICP use, management of ICP using nICP methods, and thresholds of nICP tools for escalating/de-escalating treatment after traumatic brain injury when invasive tools are not available.

Four clinical algorithms were created for escalating and de-escalating treatment based on clinical assessment, neuroimaging and nICP methods.

The SYNAPSE-ICU study, a prospective observational cohort study at 146 intensive care units (ICUs) in 42 countries, demonstrated that ICP monitoring and management varies greatly across centers and countries, and that intracranial hypertension treatment guided by monitoring might be considered in severe cases due to the potential associated improvement in long-term clinical outcomes [3].

Subsequently, an extensive reviewed protocol [i.e., the Consensus REVised ICE (CREVICE) protocol] for the management of severe TBI when ICP is not available, based on clinical and neuroimaging findings, was proposed and validated [12–14].

There are some tools for non-invasive monitoring of ICP (nICP) in TBI and other clinical conditions causing cerebral edema, and/or intracranial hypertension [15]. These devices include transcranial Doppler (TCD)

ultrasonography [16–18], transorbital ultrasonographic measurement of the optic nerve sheath diameter (ONSD) [19], automated pupillometry [20–22] and so on. They are, as a rule, usually handy, and easily deployed at the patient's bedside, particularly in low resource settings.

Until now, no guidelines have been provided for the implementation of nICP methods, together with clinical assessment with or without neuroimaging. Although published literature has shown that these tools are not accurate enough to substitute invasive methods, evidence suggests that they might help clinicians to raise the suspect or exclude intracranial hypertension [16, 17].

Therefore, the aim of this consensus was to provide recommendations for the use of nICP methods and develop algorithms for escalation and de-escalation of treatments based on clinical findings, with (as for the CREVICE Protocol) [12] or without brain CT, in TBI patients with indications for invasive ICP, when the tool is not available/adopted.

Methods

Endorsement, sponsorship and conflict of interest

The methodology, including the literature search and the generation of the recommendations, the full process and the final results of the consensus were proposed, endorsed and finally approved by the following institutions:

- The European Society of Intensive Care Medicine (ESICM)
- The Neurotraumatology Committee of the World Federation of Neurosurgical Societies (WFNS);
- The Neurotraumatology and Intensive Care Chapter of the Latin American Federation of Neurosurgical Societies (FLANC);
- The Latin American Brain Injury Consortium (LABIC);
- The Global Health Research Group in Acquired Brain and Spine Injuries (GHRG-BSI);
- The Global Neuro Foundation (GNF);
- The Foundation for Medical Emergency Research and Education (MEDITECH);
- The Society of Neurocritical Care (SNCC)
- The International Pan Arab Critical Care Medicine Society (IPACCMS)

No funding was provided by the involved societies. The face-to-face meeting in Brussels was supported by Neuroptics for travel and accommodation of the group of experts. The representations from Neuroptics were allowed to be in an adjacent area of the room for observation of the consensus, without any interaction with the panelists or the process. No donors or other outside parties influenced any portion of these recommendations. There was no industry input into guidelines development, and no consensus panel member received honoraria. The panelists completed conflict of interest forms relevant to TBI management. There were no conflicts mandating recusal of any participant.

Selection of committee members

The Steering Committee, composed by CR and AMR who served as Chairs of the Consensus, and with the Co-Chairs (FST, EP, SVG) selected the panelists after extensive discussion and search. A total of 41 expert physicians, 22 from high-income countries and 19 from low-middle income countries, were included to have a balanced global representation. Twenty-five neurointensivists, 10 neurosurgeons, and 6 neurologists certified in neurocritical care composed the panel. The physicians were chosen according to: (1) experience in the management of TBI patients with invasive and non-invasive tools, (2) active participation in research and academic activities on the topic, (3) country and gender representation, (4) active participation in societies representing low income countries. A non-voting methodologist and statistician (NH) defined the different steps of the consensus, in accordance with the rules of the Research Committee of the ESICM.

Questions and consensus development

The consensus was developed using a modified Delphi process based on the integration of evidence from the literature review and expert opinions [12]. An initial literature search with survey in low-income countries centers regarding the availability of the tools was performed to choose the most frequently used nICP estimation (a list of current methods for nICP estimation is provided in the electronic supplemental material, ESM; Table S1). The choice of the tools was based on the bedside availability, low costs (ESM Table S1) the presence of literature supporting the use of these tools to estimate nICP, and limited need of training. The panel agreed on the inclusion of the Neurologic Pupillary Index (NPi) from automated pupillometer, the pulsatility index (PI) and a nICP estimation formula based on diastolic flow velocity (FVd) from TCD/trans color Duplex Doppler (TCCD) [Mean arteria pressure (MAP) – (MAP*FVd/FVmean) + 14), and the ultrasonographic assessment of the ONSD [23–25].

Some tools were excluded for different reasons [26]. For instance, electroencephalography (EEG) [27, 28], which is a fundamental neuromonitoring tool for detecting seizures and cerebral ischemia, is not always directly correlated with ICP and not feasible/available in low

income countries. Similarly, magnetic resonance imaging, despite can provide important information on ICP, is not easily available in this context. The midline shift assessment with ultrasound (US) is also not widespread used and difficult in terms of training [29]. Considering the above, these techniques were not included in this consensus.

For each tool, separate scoping reviews were performed, and four systematic reviews with meta-analysis (TCD/TCCD based nICP, PI, ONSD and NPi) were conducted specifically focusing on the thresholds and accuracy for ICP estimation, as well as the positive and negative predictive value for each method [23–25]. For the systematic review and meta-analysis, we followed the Preferred Reporting Items for Systematic Reviews and Meta-Analysis—Protocols (PRISMA-P) guidelines [30]. The methodological plan for this systematic review was registered on PROSPERO (ID CRD42024507037) and fully described in the ESM2. The literature review and the assessment of the evidence of literature with the risk of bias and GRADING were made available to the panel through web-based files.

An initial pool of 34 questions, based on the literature search, was initially created by the Steering Committee and then discussed with the panel through an online meeting and a preliminary voting round, which allowed to refine the questions and were divided into three sections:

1. General considerations for the use of nICP methods in TBI patients.
2. Management of patients with TBI implementing nICP tools.
3. Thresholds of nICP tools for detection or exclusion of intracranial hypertension.

The questions were proposed to each panel member through a web-based system. Each question required a score system, ranging from 1 (strongly disagree) to 10 (strongly agree), and experts were also invited to provide comments to clarify their answers. The responses were analyzed by a methodologist non-voting member of the panel.

The answers providing scores were analyzed as medians and 25th and 75th percentiles, scores were clustered into low [1–3], intermediate [4–7], and high [8–10], and then re-analyzed. Both approaches were used to identify answers that provided clear-cut responses from the experts, particularly those polarized on agreement or disagreement. Correspondence analysis was used to assess if individual panel members provided specific response patterns, particularly when intermediate positions were taken. The results of the analyses were returned to the panel anonymously for information (the name of each member was replaced with a numeric code), and the same list of questions was then resubmitted to the panel in a second voting round. Based on the analysis of the second round of questions, consensus statements were formulated by the steering committee, and then resubmitted to the panel for review. The answers were analyzed to identify heterogeneity among panel members. To minimize the risk of misinterpretations of some questions and statements, individual panel members who had provided heterogeneous answer patterns were invited to review their responses and confirm or correct their vote. After the final round of voting, the consensus was finalized defining as strong recommendation (in favor or against) when more than 85% of voting members supported this position for a particular question. When votes in favor or against were in the 75–85% range, a weak recommendation was made. When the 75% threshold was not reached a "no recommendation" option was adopted.

During the face-to-face meeting, conducted in Brussels on the 8th of November 2023, methodology for literature search, the process for reaching the consensus and the approved statements were illustrated. Statements who did not reach consensus were discussed, one further statement was suggested and underwent vote. Two algorithms for defining criteria for escalating ICP treatment (considering brain CT availability) and two for de-escalation of treatment and implementing nICP tools in the CREVICE protocol [12] were discussed, voted, and approved.

The additional surveys addressed the timing of escalation/de-escalation and the weaning of ongoing therapies for intracranial hypertension considering specified combinations of clinical, imaging, and nICP parameters. These were further evaluated using a traffic light rating scheme, where green favored tapering, red opposed it, and yellow represented caution/uncertainty. By combining individual panelist's responses and color-coding, we constructed heatmaps to guide decision-making. All recommendations were incorporated into the final protocols, which was submitted for approval to all voting members.

Results

A total of 34 recommendations were provided (Table 1). Among these, 30 were strong recommendations in favor, 2 strong recommendations against, and 2 weak recommendations.

–General considerations for the use of nICP methods in TBI patients

Clear evidence is available regarding the fact that none of the available nICP tools is, at present, accurate enough

to substitute invasive tools, especially when looking at ICP as a number. However, all selected tools can be performed at bedside, and are easily available and low cost, with a background of evidence suggesting a role in the estimation of nICP [15].

Specific limitations of the methods were discussed, regarding the technique itself, the different pathophysiological mechanisms underlying every nICP tools, as well as the need of training and the feasibility of achieving good quality images, regarding ONSD or TCD, where significant intra- and inter-observer variability can occur [31, 32]. Considering the above-mentioned limitations, especially regarding accuracy, the experts agreed on the need to obtain a concordant information regarding ICP changes from at least two different nICP methods to trigger a therapeutic decision [33], and to integrate this information with clinical and neuroimaging findings (if available). In addition, the panel highlighted the importance of considering only good quality images from a trained operator who understands the pitfalls and limitations of the technique before making any decisions. Despite ONSD and TCD/TCCD require training to obtain appropriate images, recent guidelines suggest that the learning curve for both techniques is acceptable and are part of basic US skills for general and neuro intensivists [17, 29].

Serial, and whenever possible continuous measurements could be taken in consideration to assess the changes from basal values. When values of nICP are different between cerebral sides, the worst should be considered.

Finally, experts agreed that, besides the traditional indication for ICP monitoring (i.e. GCS [34] score < 9 with a positive head CT), different clinical scenarios can benefit from the use of nICP methods to assess the risk of neuroworsening and changes in cerebral dynamics (i.e., moderate TBI with positive/potentially evolutive intracranial lesions, the presence of extracranial injuries, or in severe TBI with negative CT-scan).

Recommendations

- We recommend that, in severe TBI patients (GCS < 9 [34]) with radiological signs of intracranial hypertension, when available and not contraindicated, invasive ICP monitoring should always be used over non-invasive methods *(Strong Recommendation) (Evidence based on previous Guidelines).*
- We recommend that the main tools to be used for nICP (if available) should be: NPi from automated pupillometer, PI from TCD/TCCD, nICP formula from TCD/TCCD, and ONSD *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend against the use of other nICP tools (such as EEG, tympanic membrane displacement, Doppler of retinal artery etc.) as not feasible or at present used only in research field *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that a multimodal approach including different nICP methods (at least 2 different modalities) is necessary compared to the use of a single modality for ICP assessment *(Strong Recommendation)(Very low level of evidence).*
- We recommend that nICP should be integrated in the context of neuroimaging and clinical assessment as soon as possible after hospital admission in all patients with TBI *(Strong Recommendation) (No evidence available, experts opinion).*
- In TBI patients with clinical symptoms (assessed with pupils and GCS examination [34]) and/or radiological signs of intracranial hypertension, the utilization of nICP methods (possibly integrated into multimodal monitoring strategy) should be used as a triage tool to identify patients at risk of intracranial hypertension *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend, in TBI patients with clinical symptoms (assessed with pupils and GCS examination [34]) and/or radiological signs of intracranial hypertension, the utilization of nICP methods (possibly integrated into multimodal monitoring strategy) to guide and optimize the management of intracranial hypertension *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that serial non-invasive estimations should be performed in order to assess changes in ICP *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that both the basal value of nICP and the changes from baseline should be taken into account *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that non-invasive estimation of ICP and the resulting decision of treatment should be done only on the basis of high quality images (for ONSD, TCD/TCCD) *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that, in the choice of the nICP tool, the specific limitations of each technique should be taken into consideration (i.e. no use of ONSD in case of skull base fracture or ocular lesions) *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that, among the methods proposed, none is considered as gold standard, and the choice

Table 1 Statements generated by the consensus

Statement	Level of agreement
General considerations for the use of nICP methods in TBI patients	
1. We recommend that, in severe TBI patients (GCS < 9) with radiological signs of intracranial hypertension, when available and not contraindicated, invasive ICP should always be used over non-invasive methods	*Strong Recommendation*
2. We recommend that the main tools to be used for the non-invasive estimation of ICP (if available) should be: NPi from automated pupillometer, PI from TCD/TCCD, nICP formula from TCD/TCCD, and ONSD	*Strong Recommendation*
3. We recommend against the use of other non-invasive ICP estimation tools (such as EEG, tympanic membrane displacement, Doppler of retinal artery etc..) as not feasible or at present used only in the research field	*Strong Recommendation against*
4. We recommend that a multimodal approach including different non-invasive ICP methods (at least 2 different modalities) is necessary compared to the use of a single modality for ICP assessment	*Strong Recommendation*
5. We recommend that nICP estimation should be integrated in the context of neuroimaging and clinical assessment as soon as possible after hospital admission in all patients with TBI	*Strong Recommendation*
6. In TBI patients with clinical symptoms (assessed with pupils and GCS examination) and/or radiological signs of intracranial hypertension, the utilization of nICP methods (possibly integrated into multimodal monitoring strategy) should be used as a triage tool to identify patients at risk of intracranial hypertension	*Strong Recommendation*
7. We recommend, in TBI patients with clinical symptoms (assessed with pupils and GCS examination) and/or radiological signs of intracranial hypertension, the utilization of nICP methods (possibly integrated into multimodal monitoring strategy) to guide and optimize the management of intracranial hypertension	*Strong Recommendation*
8. We recommend that serial non-invasive estimations should be performed in order to assess changes in ICP	*Strong Recommendation*
9. We recommend that both the basal value of nICP and the changes from baseline should be taken into account	*Strong Recommendation*
10. We recommend that non-invasive estimation of ICPand the resulting decision of treatment should be done only on the basis of high quality images (for ONSD, TCD/TCCD)	*Strong Recommendation*
11. We recommend that, in the choice of the nICP tool, the specific limitations of each technique should be taken into consideration (i.e. no use of ONSD in case of skull base fracture or ocular lesion)	*Strong Recommendation*
12. We recommend that, among the methods proposed, none is considered as gold standard, and the choice of the tool should be based on clinical practice and availability	*Strong Recommendation*
13. We recommend, that when values of nICP are different between cerebral sides, the worst obtained value (possibly confirmed with 2 nICP tools) should be taken into consideration for treatment	*Strong Recommendation*
14. We recommend the use of nICP (GCS < 9) also in the presence of moderate TBI (GCS 9–12) with a positive brain CT to monitor potential changes in ICP	*Strong Recommendation*
15. We recommend the use of nICP estimation also in the presence of severe TBI (GCS < 9) with negative brain CT to monitor potential changes in ICP	*Strong Recommendation*
16. We recommend the use of nICP estimation also in moderate TBI in the presence of extracranial injuries, especially when these preclude clinical assessment to monitor potential changes in ICP	*Strong Recommendation*
Management of patients with TBI implementing nICP tools with the available evidence	
17. We recommend, for the management of patients with severe TBI, clinicians to follow the general principles of the current BTF Guidelines, the Seattle consensus and algorithm for ICP management (SIBICC I) and the CREVICE protocol when ICP is not available	*Strong Recommendation*
18. We recommend that in a patient with severe TBI in the absence of invasive ICP monitoring, the criteria for determining the presence of suspected intracranial hypertension from the CREVICE protocol should be applied and non-invasive methods should be integrated into this protocol	*Strong Recommendation*
19. We recommend that, in a patient with severe TBI receiving nICP monitoring, it is not necessary to use all treatment strategies of a lower tier of the Seattle (SIBICC I) algorithm before moving to the next tier or for deescalating treatments	*Strong Recommendation*
20. We recommend that, in a patient with severe TBI receiving nICP monitoring, according to the clinical and radiological context, tiers can be skipped to advanced treatment (e.g., early decompressive craniectomy) in selected cases	*Strong Recommendation*
21. We recommend that, in a patient with severe TBI, basal treatment (Tier 0 from SIBICC I) with associated nICP assessment should be performed as first instance	*Strong Recommendation*
22. We recommend that, if available, concordance of at least 2 tools for estimation of nICP should be used to trigger or de-escalate treatment for intracranial hypertension	*Strong Recommendation*
23. We recommend that weaning the therapy intensity level should be considered when neuroimaging, clinical picture improve and non-invasive methods suggest a controlled/improved ICP	*Strong Recommendation*
24. We recommend, in severe TBI patients (GCS < 9) that nICP estimation should be performed continuously or at least over a prolonged period of time, if available (refer only to TCD)	*Strong Recommendation*
25. We recommend, in severe TBI patients (GCS < 9) that nICP estimation with NPi, TCCD (PI and/or nICP formulae) and/or ONSD should be performed at least every 2–4 h	*Weak Recommendation*
26. We recommend, in moderate TBI patients GCS 9-12 that nICP estimation with NPi, TCCD (PI and or nICP formulae) and/or ONSD should be performed at least every 4–6 h	*Weak Recommendation*

Table 1 (continued)

Statement	Level of agreement
Thresholds of nICP tools for detection/exclusion of intracranial hypertension	
27. When employing automated pupillometry, we recommend NPi < 3 to be used (in combination with at least another tool) to suspect the presence of elevated ICP, and NPi ≥ 4 to rule out the presence of elevated ICP	*Strong Recommendation*
28. When using ONSD, we recommend considering a threshold of 6 mm as a potential marker of intracranial hypertension or for excluding it	*Strong Recommendation*
29. For TCD/TCCD use, we suggest considering a threshold of PI of 1.3 in conjunction with a FVd < 20 cm/sec as a threshold for considering CBF changes potentially associated to high ICP, or for excluding it	*Strong Recommendation*
30. When using nICP-TCD/TCCD, we recommend a threshold of 20–22 mmHg to exclude or raise the suspicion of intracranial hypertension	*Strong Recommendation*
31. We recommend that, to raise/exclude the suspect of intracranial hypertension, a change from basal level of NPi of at least 1 should be considered as a potential sign of ICP modification	*Strong Recommendation*
32. We recommend that, to raise/exclude the suspect of intracranial hypertension, a change from basal level of ONSD of at least 0.5mm, should be considered as a potential sign of ICP modification	*Strong Recommendation*
33. We recommend that to raise/exclude the suspect of intracranial hypertension, a change from basal level of PI of at least 0.5 should be considered as a sign of CBF modification potentially related to ICP shift	*Strong recommendation*
34. The use of nICP estimated through TCD/TCCD as variations from baseline values, is not recommended for estimation of changes in ICP	*Strong Recommendation against*

Abbreviations: *ICP* intracranial pressure, *TBI* traumatic brain injury, *GCS* Glasgow Coma Scale, *NPi* Neurologic Pupillary index, *PI* pulsatility index, *TCD* Transcranial Doppler, *TCCD* Transcranial Color Duplex Doppler, *ONSD* optic nerve sheath diameter, *ICP* intracranial pressure, *nICP* non invasive intracranial pressure, *EEG* electroencephalography; *CBF* cerebral blood flow, *BTF* Brain Trauma Foundation, *SIBICC* Seattle International Severe Traumatic Brain Injury Consensus Conference, *CREVICE Consensus Revised Imaging and Clinical Examination*

of the tool should be based on clinical practice and availability *(Strong Recommendation) (No evidence available, experts opinion).*

- We recommend, that when values of nICP are different between cerebral sides, the worst obtained value (possibly confirmed with two different non-invasive tools) should be taken into consideration for treatment *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend the use of nICP also in the presence of moderate TBI (GCS 9–12 [34]) with a positive brain CT to monitor potential changes in ICP *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend the use of nICP also in the presence of severe TBI (GCS < 9 [34]) with negative brain CT to monitor potential changes in ICP *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend the use of nICP also in moderate TBI in the presence of extracranial injuries, especially when these preclude clinical assessment to monitor potential changes in ICP *(Strong Recommendation) (No evidence available, experts opinion).*

– Management of patients with TBI implementing nICP tools with the available evidence

As previously mentioned, this protocol aims to be an integration of previous evidence, expert opinion and guidelines. The general principles for the management of severe TBI with intracranial hypertension should follow the general criteria of Brain Trauma Foundation (BTF) guidelines [5] and the SIBICC consensus and algorithm [9]. The experts highlighted the fact that the general concept of a stepwise approach should be generally maintained, starting from a tier 0 treatment, aiming to optimize physiology, and then progressively increase the intensity of treatment using more aggressive and risky strategies. However, according to nICP, clinical and radiological findings, some tiers can be skipped according to physician's judgment. This reflects the Seattle Consensus principles [9] which suggests the possibility to skip to advanced treatments in some conditions, in particular related to local availabilities. This is even more important in low-income countries where there is a lack of resources and possibility to perform all the tiers. However, it is important to highlight that clinicians should find a balance in order to avoid overtreatment. Among each tier, there is not a priority for clinicians in using one strategy over another, always applying clinical judgment. nICP should be integrated with clinical and CT findings according to the CREVICE protocol to assess the need to escalate or de-escalate treatments [12]. Only weak agreement was obtained regarding the temporal assessment of nICP. This is related to the lack of evidence on this point. These statements are aimed to balance a pragmatic clinical approach and clinical benefits for the patients.

Recommendations

- We recommend, for the management of patients with severe TBI, clinicians to follow the general principles of the current BTF guidelines [5], the Seattle consensus and algorithm for ICP management (SIBICC I) [9] and the CREVICE protocol when invasive ICP is not available [12] *(Strong Recommendation) (Evidence based on previous Guidelines).*
- We recommend that in a patient with severe TBI in the absence of invasive ICP monitoring, the criteria for determining the presence of suspected intracranial hypertension from the CREVICE protocol should be applied and non-invasive methods should be integrated into this protocol [12] *(Strong Recommendation) (Evidence based on previous Guidelines, experts opinion).*
- We recommend that, in a patient with severe TBI receiving nICP monitoring, it is not necessary to use all treatment strategies of a lower tier of the Seattle (SIBICC I) algorithm before moving to the next tier or for de-escalating treatments [9] *(Strong Recommendation) (Evidence based on previous Guidelines, experts opinion).*
- We recommend that, in a patient with severe TBI receiving nICP, according to the clinical and radiological context, tiers can be skipped to advanced treatment (e.g., early decompressive craniectomy in selected cases) *(Strong Recommendation) (Evidence based on previous Guidelines, experts opinion).*
- We recommend that, in a patient with severe TBI, basal treatment (Tier 0 from SIBICC I [9]) with associated nICP assessment should be performed as first instance *(Strong Recommendation) (Evidence based on previous Guidelines, experts opinion).*
- We recommend that, if available, concordance of at least 2 tools for estimation of nICP should be used to trigger or de-escalate treatment for intracranial hypertension. *(Strong Recommendation) (Very low level of evidence).*
- We recommend that weaning the therapy intensity level should be considered when neuroimaging and clinical picture improve and non-invasive methods suggest a controlled/improved ICP *(Strong Recommendation) (Evidence based on previous Guidelines, experts opinion).*
- We recommend, in severe TBI patients (GCS < 9 [34]) that nICP estimation should be performed continuously or at least over a prolonged period of time, if available (refer only to TCD) *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend, in severe TBI patients (GCS < 9 [34]) that nICP estimation with NPi, TCCD (PI and/or nICP formulae) and/or ONSD should be performed at least every 2–4 h *(Weak Recommendation) (No evidence available, experts opinion).*
- We recommend, in moderate TBI patients (GCS 9–12 [34]) that nICP estimation with NPi, TCCD (PI and or nICP formulae) and/or ONSD should be performed at least every 4–6 h *(Weak Recommendation) (No evidence available, experts opinion).*

– Thresholds of nICP tools for detection/exclusion of intracranial hypertension

Our four systematic reviews and meta-analysis aimed to assess the best thresholds of the different techniques, providing insights on their accuracy, as well as their positive and negative predictive values (PPV, NPV) to raise the suspicion or exclude increased ICP. The whole methodology and results are presented in ESM 2.

Among these, NPi was evaluated in two studies [33, 35], PI in seven studies [33, 37–41], ONSD in 20 studies [33, 39, 40, 42–58] and nICP with TCD/TCCD in five studies [33, 38, 59–61].

Regarding NPi, the optimal cut-off value was 3.96 (Sensitivity 0.68 [0.67; 0.69]; specificity 0.68 [0.67–0.68]). We then specifically evaluated the row data of the two studies available to find the thresholds with acceptable NPV and PPV, respectively [33, 35].

According to Pansell et al. [35] NPi < 4 has PPV 12% and NPV 92%, thus showing good performance in excluding increased ICP. According to Robba et al. [33] NPi < 3 has a PPV 74% for high ICP while NPi < 3.9 has NPV 76% to exclude high ICP.

However, considering that according to Robba et al. [33] the combined AUC of NPi with at least another tool to predict high ICP improves accuracy and also PPV (AUC > 0.85), and in our consensus we recommend to use two combined methods, this was included in both the escalation and de-escalation protocols.

Regarding PI, the pooled best cut-off was 1.28 (sensitivity 0.737 [0.366; 0.947]; specificity 0.737 [0.366; 0.947]). However, it is important to highlight that PI can be strongly influenced by changes in arterial blood pressure and carbon dioxide, thus being more an indicator of cerebral blood flow (CBF) and perfusion and only indirectly of ICP. The panel agreed on including this tool to be used to raise the tendency to suspect or exclude intracranial hypertension, adding, as additional value, FVd > 20 cm/sec for cerebral perfusion, to reduce the risk of false positives.

For ONSD, the best cut-off of 5.9 mm (sensitivity 0.83 [0.78; 0.87], specificity 0.83 [0.78; 0.87]) was obtained, and for nICP-TCD of 19.6 mmHg (sensitivity 0.70 [0.46; 0.87], specificity 0.70 [0.53; 0.83). According to this, ONSD, PI and nICP-TCD were considered as acceptable markers to raise the suspicion or to exclude increased ICP, and therefore to be implemented in both the escalating and de-escalating algorithms.

Finally, no data were available regarding the predictive value of changes of these nICP tools from basal measurement to confirm or exclude intracranial hypertension. Therefore, the statements regarding changes from basal values are based only on expert opinions and further studies are required to confirm these findings.

Recommendations

- When employing automated pupillometry, recommend NPi < 3.0 to be used (in combination with at least another tool) to suspect the presence of elevated ICP, and NPi ≥ 4.0 to rule out the presence of elevated ICP *(Strong Recommendation) (Very low level of evidence).*
- When using ONSD, we recommend considering a threshold of 6 mm as a potential marker of intracranial hypertension or for excluding it *(Strong Recommendation) (Low level of evidence).*
- For TCCD use, we suggest considering a threshold of PI of 1.3 in conjunction with a FVd < 20 cm/sec as a threshold for considering low CBF potentially associated to high ICP, or for excluding it *(Strong Recommendation) (Low level of evidence).*
- When using nICP-TCCD, we recommend a threshold of 20–22 mmHg to exclude or raise the suspicion of intracranial hypertension *(Strong Recommendation) (Low level of evidence).*
- We recommend that, to raise/exclude the suspect of intracranial hypertension, a change from basal level of NPi of at least 1 should be considered as a potential sign of ICP modification *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that, to raise/exclude the suspect of intracranial hypertension, a change from basal level of ONSD of at least 0.5mm, should be considered as a potential sign of ICP modification *(Strong Recommendation) (No evidence available, experts opinion).*
- We recommend that to raise/exclude the suspect of intracranial hypertension, a change from basal level of PI of at least 0.5 should be considered as a sign of CBF modification potentially related to ICP shift *(Strong Recommendation) (No evidence available, experts opinion).*
- The use of nICP through TCD/TCCD as variations from baseline values, is not recommended for estimation of changes in ICP *(Strong Recommendation) (No evidence available, experts opinion).*

– Clinical algorithms for escalation and de-escalation of treatment

Clinical algorithms for escalation of therapy for intracranial hypertension (with and without CT availability) are presented in Figs. 1, 2, 3, and 4. For definition and timing of escalation /de-escalation of tiers, we referred to the CREVICE protocol definitions [12].

The criteria for suspecting the risk of intracranial hypertension were defined according to the CREVICE protocol [12], which was not altered, with the addition the results of the B-ICONIC consensus as the presence of one major or two minor criteria, in the presence of CT availability, or in the presence of 2 minor criteria when CT is not available.

Major criteria:

1. Compressed cisterns (Marshall CT score—diffuse injury III [62])
2. Midline shift > 5 mm (Marshall CT score—diffuse injury IV [62])
3. Non-evacuated mass lesion [62].

Minor criteria

1. Glasgow Coma Scale (GCS) motor score ≤ 4 (not improving) [34].
2. Pupillary asymmetry.
3. Abnormal pupillary reactivity.
4. CT Marshall classification of diffuse injury II (i.e., basal cisterns are present with midline shift 0–5 mm and/or high-or mixed-density lesion ≤ 25 cm^3) [62]
5. nICP abnormal, defined as 2 altered nICP methods:

- nICP TCD/ TCCD > 20–22 mmHg (any side)
- ONSD > 6 mm (any side)
- PI > 1.3 with FVd < 20 cm/s (any side)
- NPi < 3 (any side)
- Reduction of NPi from basal value of 1 (any side)
- Increase of ONSD from basal of 0.5 mm (any side)
- Increase of PI from basal of 0.5 (any side)

Criteria for escalating treatment or adding an additional treatment were defined according to the CREVICE protocol [12], thus providing great importance to the presence of altered CT findings, and the results of the B-ICONIC consensus as the presence of one major

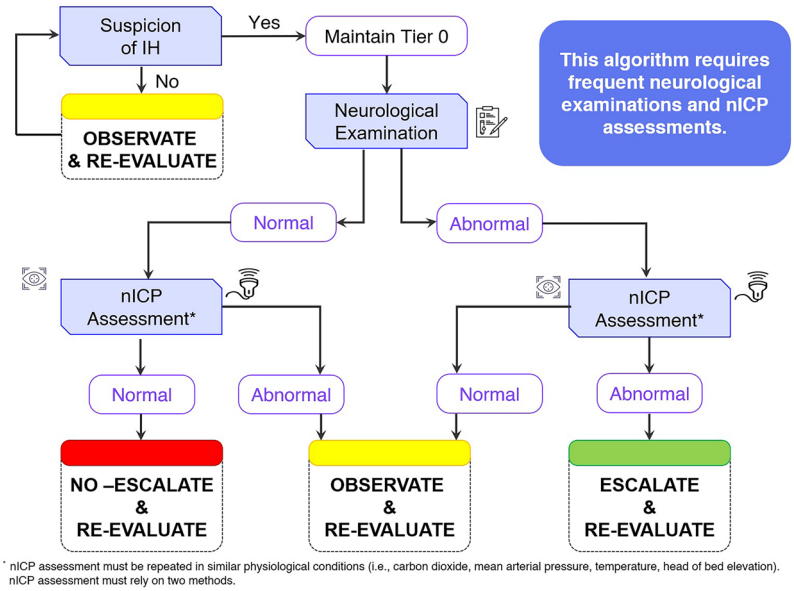

Fig. 1 Algorithm for escalation of treatment without CT scan. Abbreviations: *nICP* non-invasive intracranial pressure, *Neuro-Exam* neurological examination, *N.* normal, *Ab.* abnormal or stable. Red light = no/stop and re-evaluate. Green light = yes/proceed and re-evaluate. Yellow light = re-evaluate. [1]As for CREVICE and B-ICONIC consensus definition. [2]TIER 0 of the SIBICC. [3]Pupils' examination and Glasgow Coma Scale (GCS) score. ABNORMAL = new pupillary asymmetry defined as interval development of pupil asymmetry of > 2mm or bilateral mydriasis, new loss of pupil reactivity, new decrease in the motor GCS of 1 or more points, new focal motor deficit, herniation syndrome (e.g., Cushing's triad). [4]ABNORMAL = defined as 2 altered nICP methods: NPi < 3, nICP-TCCD > 20-22mmHg, Optic Nerve Sheath Diameter (ONSD) > 6, Pulsatility Index (PI) > 1.3 with Diastolic Flow Velocity (FVd) < 20cm/sec, reduction of NPi from basal value of 1, increase of ONSD from basal of 0.5mm, increase of PI from basal of 0.5. [5]Defined as adding a treatment within the same or next tier. [6]Every 2–4 h for severe TBI, every 4–6 for moderate TBI

or two minor criteria, in the presence of CT availability, or in the presence of two minor criteria when CT is not available (Figs. 1, 2).

Major criteria:

- no improvement or worsening on follow-up CT imaging (Marshall III, IV and VI) [62]— (all brain CT scans performed following mass lesion evacuation will be re-classified using the non-surgical component of the Marshall score [62] as in the CREVICE protocol [12]: EMS-III and EMS-IV, as for: compressed cisterns [Marshall CT score—diffuse injury III [62]]; midline shift > 5 mm [(Marshall CT score—diffuse injury IV [62]]; non-evacuated mass lesion [62]).

Minor criteria:

- decrease in the motor GCS [34] of 1 or more points.
- new loss of pupil reactivity.
- new development of pupil asymmetry of > 2mm or bilateral mydriasis.
- new focal motor deficit.
- herniation syndrome (e.g., Cushing's triad).
- no improvement or worsening of at least 2 nICP tools (as indicated above).

Criteria and timing for de-escalating of treatment were defined according to the CREVICE protocol [12] and the results of the B-ICONIC consensus as the presence of one major or two minor criteria, in the presence of CT availability, or in the presence of two minor criteria when CT is not available. Figures 3 and 4 show the clinical algorithm and heatmaps for de-escalation therapy (with and without CT availability).

Major criteria for de-escalation:

- improvement or stabilization on follow-up CT imaging (Marshall III, IV and VI) [62] – (*all brain CT scans performed following mass lesion evacuation will be re-classified using the non-surgical component of the Marshall score [62] as in the CREVICE protocol [12]: EMS-III and EMS-IV).

Minor criteria:

- increase in the motor GCS [34] of 1 or more points.
- new gain of pupil reactivity.
- improvement of pupil asymmetry or bilateral mydriasis.
- improvement of focal motor deficit.

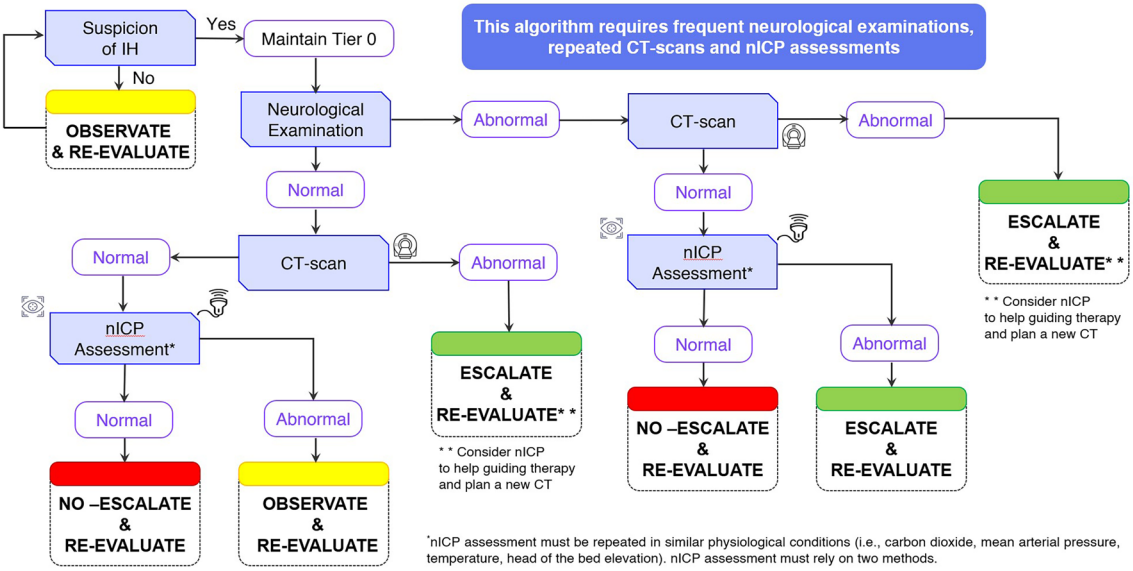

Fig. 2 Algorithm for escalation of treatment when CT scan is available. Abbreviations: *nICP* non-invasive intracranial pressure, *Neuro-Exam* neurological examination, *CT* computed tomography, *N.* normal, *Ab.* abnormal. Red light = no/stop and re-evaluate. Green light = yes/proceed and re-evaluate. Yellow light = re-evaluate. [1]As for CREVICE and B-ICONIC consensus definition. [2]TIER 0 of the SIBICC. [3]Pupils' examination and Glasgow Coma Scale (GCS) score. ABNORMAL = new pupillary asymmetry defined as interval development of pupil asymmetry of > 2 mm or bilateral mydriasis, new loss of pupil reactivity, new decrease in the motor GCS of 1 or more points, new focal motor deficit, herniation syndrome (e.g., Cushing's triad). [4]ABNORMAL = Marshall CT score of III, IV, VI, evacuated mass lesion (EMS)-III, and EMS-IV. [5]ABNORMAL = defined as 2 altered nICP methods: NPi < 3, nICP TCCD > 20–22 mmHg, Optic Nerve Sheath Diameter (ONSD) > 6, Pulsatility Index (PI) > 1.3 with Diastolic Flow Velocity (FVd) < 20 cm/sec, reduction of NPi from basal value of 1, increase of ONSD from basal of 0.5 mm, increase of PI from basal of 0.5. [6]Defined as adding a treatment within the same or next tier. [7]Every 2–4 h for severe TBI, every 4–6 for moderate TBI

– resolution of herniation syndrome (e.g., Cushing's triad).
– improvement of at least 2 nICP tools, in particular:

  - NPI ≥ 4
  - nICP TCCD < 20–22 mmHg
  - ONSD < 6mm
  - PI < 1.3 with FVd > 20 cm/sec
  - Increase of NPi from basal value of 1
  - Reduction of ONSD from basal of 0.5 mm
  - Reduction of PI from basal of 0.5

The traffic lights heatmaps (ESM 3) describe the decision strategy for weaning from ongoing treatment based on the CT scan (when available), the clinical status [patient's GCS motor score [34] and pupillary examination], and nICP. Importantly, the heatmaps do not include the duration of stabilization, which was discussed among the panel to be at least of 24 h. Re-evaluation is, however, recommended in any case.

Discussion and perspectives

This consensus provides several recommendations and comprehensive algorithms for TBI management in settings where indications for invasive ICP are met, but the tool is not available/adopted.

Notably, invasive methods must always be considered the first choice and the gold standard in this setting, and therefore, these protocols should not be considered as an alternative approach when invasive ICP monitoring is available. Non-invasive methods cannot define ICP "as a number", but may have the ability to exclude or raise the suspicion of increased ICP, and to better understand intracranial pathophysiological changes [15]. Their use and application are increasing over the last decades, especially in low-middle income countries, as these are easily available, repeatable, low costs and safe [15, 63]. Importantly, each of the techniques suggested has important limitations in terms of accuracy, and should always be used in combination, in order to reduce the risk of error and to improve the positive and negative predictive values. According to the results of our meta-analysis, this is particularly true for NPi from pupillometry, which showed the lowest performance, and should therefore always be used together with another tool as suggested by our consensus. Also, further studies are needed to assess the accuracy of thsee methods to estimate ICP [64], and a very recent study has challenged the application of NPi to assess ICP.

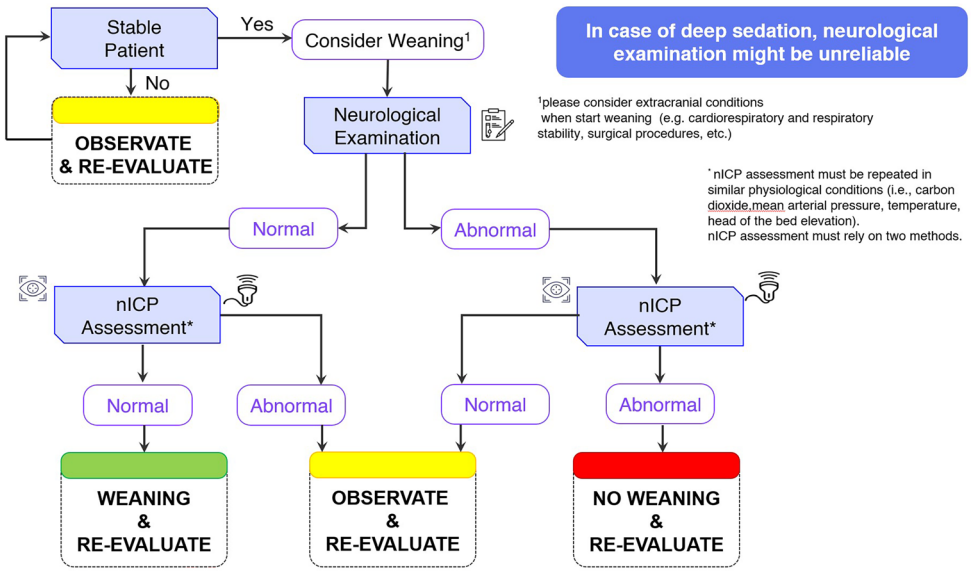
Stable Patient
Yes
Consider Weaning[1]
In case of deep sedation, neurological examination might be unreliable
No
OBSERVATE & RE-EVALUATE
Neurological Examination
[1]please consider extracranial conditions when start weaning (e.g. cardiorespiratory and respiratory stability, surgical procedures, etc.)
* nICP assessment must be repeated in similar physiological conditions (i.e., carbon dioxide,mean arterial pressure, temperature, head of the bed elevation). nICP assessment must rely on two methods.
Normal
Abnormal
nICP Assessment*
nICP Assessment*
Normal
Abnormal
Normal
Abnormal
WEANING & RE-EVALUATE
OBSERVATE & RE-EVALUATE
NO WEANING & RE-EVALUATE

Fig. 3 Algorithm for de-escalation of treatment without CT scan. Abbreviations: *SICH* suspected intracranial hypertension, *nICP* non-invasive intracranial pressure, *Neuro-Exam* neurological examination, *N.* normal, *Ab.* abnormal (or stable). Red light = no/stop and re-evaluate. Green light = yes/proceed and re-evaluate. Yellow light = re-evaluate. Green snail = cautiously proceed and re-evaluate—[1]As for CREVICE and B-ICONIC consensus definition. [2]TIER 0 of the SIBICC. [3]Pupils' examination and Glasgow Coma Scale (GCS) score. ABNORMAL = new pupillary asymmetry defined as interval development of pupil asymmetry of > 2 mm or bilateral mydriasis, new loss of pupil reactivity, new decrease in the motor GCS of 1 or more points, new focal motor deficit, herniation syndrome (e.g., Cushing's triad). [4]ABNORMAL = defined as 2 altered nICP methods: Neurological Pupillary Index (NPi) ≥ 4, Optic Nerve Sheath Diameter (ONSD) > 6, Pulsatility Index (PI) > 1.3 with Diastolic Flow Velocity (FVd) < 20 cm/sec, nICP-TCCD > 20-22 mmHg, reduction of NPi from basal value of 1, increase of ONSD from basal of 0.5 mm, increase of PI from basal of 0.5. [5]Every 2–4 h for severe TBI, every 4–6 for moderate TBI

Importantly, ONSD can be estimated also with CT with good accuracy [65]. CT is not feasible for repeated, bedside assessment of ONSD and ICP. However, the value of ONSD obtained from CT (requested in daily clinical practice) can be compared with the value obtained with US.

Some of these tools require training such as ONSD and TCD. Recently, automated devices, able to obtain windows for the assessment of middle cerebral artery flow velocity without technical expertise, has been created. This technology (i.e., Novasignal) is a future promising tool for the ICU.

In addition, the context of nICP measurement is important. For example, measurement with a head of the bed elevation to 30° would seem sensible; particularly, when measuring nICP in daily clinical practice, it is recommended to use consistent patient positioning [66]. Finally, when ICP rises, one of the compensatory mechanisms is an increase in venous blood flow into the jugular venous bulb [58]. Despite venous Doppler has been used to assess ICP, the available data are too preliminary, and the technique seems too difficult to be applied in this context.

Despite these issues, we still believe our consensus provides potentially important information which, together with neuroradiological and clinical findings [67], can help in decision making when invasive ICP is not available. Importantly, as shown in the clinical algorithms proposed, radiological findings, if available, and clinical assessment have always to be taken in consideration before using non-invasive tools.

This consensus should be considered as a potential supplement to empirical evidence, but should not be read as a potential medico-legal document describing what constitutes adequate management by an intensivist.

The risks and benefits of potentially applying this protocol are still unknown; therefore, no implication should be made as to the advisability of following this protocol in any individual case, and this can be used as a template and adapted/modified according to clinical situation and local environments. Importantly, these results have to be taken with caution, especially regarding the thresholds to trigger treatment, as these are based on low-quality evidence, and non-invasive methods present important methodological limitations [68, 69]. In addition, this consensus relies on a validated protocol—the CREVICE study [12]—but the implementation of nICP methods has not been validated on this context. Therefore, further studies are necessary to validate this consensus in the clinical practice in large observational and randomized

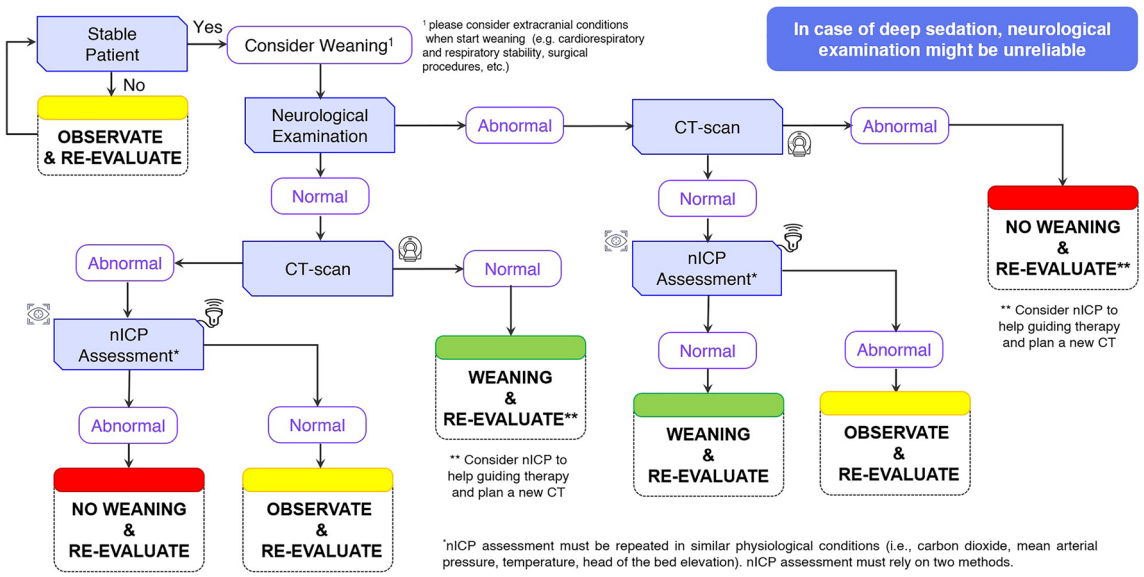
Stable Patient
Yes
Consider Weaning[1]
[1] please consider extracranial conditions when start weaning (e.g. cardiorespiratory and respiratory stability, surgical procedures, etc.)
In case of deep sedation, neurological examination might be unreliable
No
OBSERVATE & RE-EVALUATE
Neurological Examination
Abnormal
CT-scan
Abnormal
Normal
Normal
NO WEANING & RE-EVALUATE**
** Consider nICP to help guiding therapy and plan a new CT
Abnormal
CT-scan
Normal
nICP Assessment*
nICP Assessment*
Normal
Abnormal
WEANING & RE-EVALUATE**
** Consider nICP to help guiding therapy and plan a new CT
Abnormal
Normal
WEANING & RE-EVALUATE
OBSERVATE & RE-EVALUATE
NO WEANING & RE-EVALUATE
OBSERVATE & RE-EVALUATE
*nICP assessment must be repeated in similar physiological conditions (i.e., carbon dioxide, mean arterial pressure, temperature, head of the bed elevation). nICP assessment must rely on two methods.

Fig. 4 Algorithm for de-escalation of treatment when CT scan is available. Abbreviations: *SICH* suspected intracranial hypertension, *nICP* non-invasive intracranial pressure, *Neuro-Exam* neurological examination, *CT* computed tomography, *N.* normal, *Ab.* abnormal. Red light = no/stop and re-evaluate. Green light = yes/proceed and re-evaluate. Yellow light = re-evaluate. Green snail = cautiously proceed and re-evaluate—[1]as for CREVICE and B-ICONIC consensus definition. [2]pupils' examination and Glasgow Coma Scale (GCS) score. ABNORMAL = new pupillary asymmetry defined as interval development of pupil asymmetry of > 2 mm or bilateral mydriasis, new loss of pupil reactivity, new decrease in the motor GCS of 1 or more points, new focal motor deficit, herniation syndrome (e.g., Cushing's triad). [3]ABNORMAL = Marshall CT score of III, IV, VI, evacuated mass lesion (EMS)-III, and EMS-IV. [4]ABNORMAL = defined as 2 altered nICP methods: Neurological Pupillary Index (NPi) ≥ 4, Optic Nerve Sheath Diameter (ONSD) > 6, Pulsatility Index (PI) > 1.3 with Diastolic Flow Velocity (FVd) < 20 cm/sec, nICP-TCCD < 20–22 mmHg, reduction of NPi from basal value of 1, increase of ONSD from basal of 0.5 mm, increase of PI from basal of 0.5. [5]Every 2–4 h for severe TBI, every 4–6 for moderate TBI

studies (ESM4). Furthermore, more research is needed to better understand the role of other nICP tools which are currently under investigation (i.e., Brain4care [70]) or to improve the accuracy of the nICP tools included in this Consensus.

Conclusions

The goal of the B-ICONIC recommendations is to fill the gap between the currently published evidence-based guidelines and clinical practice in the specific condition of unavailability of invasive ICP methods, as well as to serve as research agenda for the creation of validation studies aimed to assess whether the implementation of nICP methods can help in clinical practice.

The experts included are clinically active and daily users of the nICP tools discussed, with a long-term experience in TBI management in different clinical and economical settings.

As consequence, these recommendations can potentially be applied in different contexts and can be adapted and modified by single centers according to local needs and expertise, and can serve as tools for the design of research projects and trials for their validation.

Supplementary Information
The online version contains supplementary material available at https://doi.org/10.1007/s00134-024-07756-2.

Author details
[1] IRCCS Ospedale Policlinico San Martino, Genoa, Italy. [2] Department of Surgical Science and Integrated Diagnostic, University of Genova, Genoa, Italy. [3] Department of Anesthesia and Intensive Care, Parma University Hospital, Parma, Italy. [4] Neurosciences and Intensive Care Department, Clínica del Country, Bogotá, Colombia. [5] Universidad del Rosario, Bogotá, Colombia. [6] Faculty of Medicine, Health Sciences Center, Kuwait University, Kuwait City, Kuwait. [7] Department of Anesthesiology and Intensive Care, Hospital Sultan Abdul Halim, Kedah, Malaysia. [8] Division of Neurological Surgery, Department of Surgery, College of Medicine, University of Ibadan, Ibadan, Nigeria. [9] Department of Neurological Surgery, University College Hospital, Ibadan, Nigeria. [10] Department of Intensive Care Medicine, Maastricht University Medical Center, Maastricht, The Netherlands. [11] Department of Neurology, University of São Paulo, São Paulo, Brazil. [12] Department of Surgery, University of Valencia, Valencia, Spain. [13] Department Anesthesiology and Surgical-Trauma Intensive Care, University Clinic Hospital, Valencia, Spain. [14] Department of Neurosurgery, St. Antonio and Biagio and Cesare Arrigo Hospital, Neurosurgery Unit, Alessandria, Italy. [15] Centre Hospitalier Universitaire Grenoble Alpes, Grenoble Institut des Neurosciences, Pôle Anesthésie Réanimation, Grenoble Alpes University, Grenoble, France. [16] Universidad Pontificia Javeriana, Cali, Colombia. [17] Department of Intensive Care, Hospital Erasme, Universitè Libre De Bruxelles, Brussels, Belgium. [18] Department of Neurology, University of Texas Southwestern Medical Center, Dallas, USA. [19] School of Medicine and Surgery, University of Milano-Bicocca, Monza, Italy. [20] Division of Neurosurgery, Department of Clinical Neurosciences, Brain Physics Laboratory, University of Cambridge, Cambridge, UK. [21] Pôle Anesthésie-Réanimation, Inserm, UMR 1214, Toulouse

Neuroimaging Center, ToNIC, Université Toulouse 3-Paul Sabatier, CHU de Toulouse, 31059 Toulouse, France. [22] Departamento Medicina Critica, Unidad de Cuidados Neurointensivos, Sanatorio Pasteur, Catamarca, Argentina. [23] Department of Neurology, Baylor College of Medicine, Houston, TX, USA. [24] Department of Neurosurgery, National Institute for Mental Health and Neurosciences (NIMHANS), Bangalore, India. [25] Hospital Eugenio Espejo and Escuela de Medicina de la Universidad San Francisco de Quito, Quito, Ecuador. [26] Department of Neurology, Saarland University Medical Center, Homburg, Germany. [27] Unidad de Terapia Intensiva, Hospital Civil Fray Antonio Alcalde, Universidad de Guadalajara, Coronel Calderón 777, El Retiro, Guadalajara, Jalisco, Mexico. [28] Department and Laboratory of Intensive Care Medicine, University Hospitals Leuven and KU, Louvain, Belgium. [29] Department of Neurosurgery, Singapore General Hospital, Singapore, Singapore. [30] Unidad de Cuidados Intensivos, Clinicas AUNA, Chiclayo, Peru. [31] Department of Neuroanaesthesiology and Critical Care, All India Institute of Medical Sciences, New Delhi, India. [32] Department of Medical and Surgical Specialties, Radiological Sciences and Public Health, University of Brescia, Brescia, Italy. [33] Department of Anesthesia, Critical Care and Emergency, Spedali Civili University Hospital, Brescia, Italy. [34] University of Medical Sciences of Havana, Havana, Cuba. [35] Department of Neurology, Cooper Medical School of Rowan University, Camden, NJ, USA. [36] Department of Anesthesiology, Tribhuvan University Teaching Hospital, Maharajgunj, Kathmandu, Nepal. [37] Department of Neurosurgery, National Institute of Mental Health and Neurosciences, Bangalore, India. [38] University of Southern California, Los Angeles, USA. [39] Neurosurgery Division, Department of Surgery, College of Health Sciences, Addis Ababa University, Addis Ababa, Ethiopia. [40] Hospital Dr. Darío Contreras, Santo Domingo, República Dominicana. [41] Hospital Nacional Professor Alejandro Posadas, Buenos Aires, Argentina. [42] Neuro Intensive Care Unit, Tan Tock Seng Hospital, Singapore, Singapore. [43] Department of Neurosurgery, University of São Paulo, São Paulo, Brazil. [44] Global Health Research Group in Acquired Brain and Spine Injuries, Cambridge, UK. [45] Neurosciences Institute, Universidad El Bosque, Bogota, Colombia. [46] MEDITECH Foundation, Cali, Colombia. [47] Anesthesia and Intensive Care, IRCCS for Oncology and Neuroscience, Policlinico San Martino, Genoa, Italy. [48] Mental Health and Neuroscience Research Institute, University Maastricht, Maastricht, The Netherlands. [49] Faculty of Medicine, Nursing and Health Sciences, Monash University, Melbourne, Australia.

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Data availability
Row data of the systematic review and of the Delphi process are available after request to the PI.

Declarations

Conflicts of interest
SB-DC serves as a scientific advisor for brain4care.CR received fees as speaker from Edwards, and Integra. GC received consulting fees from Integra and Neuroptics.

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